Registration Decision RD2012-18

Extract of *Reynoutria sachalinensis*

(publié aussi en français)

28 May 2012

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6604-E2
Ottawa, Ontario
K1A 0K9

Internet: pmra.publications@hc-sc.gc.ca
healthcanada.gc.ca/pmra
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra.infoserv@hc-sc.gc.ca

Canada

ISSN: 1925-0932 (print)
1925-0940 (online)

Catalogue number: H113-25/2012-18E (print version)
H113-25/2012-18E-PDF (PDF version)

© Her Majesty the Queen in Right of Canada, represented by the Minister of Health Canada, 2012

All rights reserved. No part of this information (publication or product) may be reproduced or transmitted in any form or by any means, electronic, mechanical, photocopying, recording or otherwise, or stored in a retrieval system, without prior written permission of the Minister of Public Works and Government Services Canada, Ottawa, Ontario K1A 0S5.

Registration Decision for Extract of *Reynoutria sachalinensis*

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of *Reynoutria sachalinensis* Bioprotectant Technical and Regalia Maxx Biofungicide Liquid Concentrate, containing the technical grade active ingredient extract of *Reynoutria sachalinensis*, to suppress a variety of diseases on field and greenhouse edible crops and ornamentals.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document[1] Proposed Registration Decision PRD2011-14, *Extract of Reynoutria sachalinensis*. This Registration Decision[2] describes this stage of the PMRA's regulatory process for extract of *Reynoutria sachalinensis* and summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2011-14. This decision is consistent with the proposed registration decision stated in PRD2011-14.

For more details on the information presented in this Registration Decision, please refer to the Proposed Registration Decision PRD2011-14, *Extract of Reynoutria sachalinensis* that contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[3] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

---

1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

3 "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act*.

4 "Value" as defined by subsection 2(1) of *Pest Control Products Act*".the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact".

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What Is Extract of *Reynoutria sachalinensis*?

The active ingredient is a plant extract from the giant knotweed plant (*Reynoutria sachalinensis*). When sprayed on plants, the extract activates Induced Systemic Resistance (ISR), an internal defence mechanism in plants that prevents growth of certain plant pathogens. The reaction within the plant suppresses diseases on ornamental plants, wheat, cucurbits, tomatoes, grapes and strawberries.

Health Considerations

Can Approved Use of Extract of *Reynoutria sachalinensis* Affect Human Health?

Extract of *Reynoutria sachalinensis* is unlikely to affect human health when used according to label directions.

Potential exposure to extract of *Reynoutria sachalinensis* may occur when handling and applying the product or when people enter a freshly treated site. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

The technical grade active ingredient, extract of *Reynoutria sachalinensis,* is anticipated to be of low acute toxicity by the oral, dermal and inhalation routes and minimally irritating to eyes and skin, and not a skin sensitizer. There is no information available in the published scientific literature that suggests extract of *Reynoutria sachalinensis* is carcinogenic, genotoxic, neurotoxic or is a developmental/reproductive toxicant. Moreover, the plant has long been used as a food ingredient and in medicinal products, in some parts of the world, with a history of safe consumption.

The end-use product is of low acute toxicity by oral, dermal, and inhalation routes, is moderately irritating to eyes, mildly irritating to skin, and is not a dermal sensitizer. Due to the irritation potential of the end-use product and the likely exposure of workers and commercial applicators to it via inhalation and contact with skin and eyes, personal protective equipment, precautionary statements, and a restricted-entry statement are required on the label to mitigate any exposure concerns.

Residues in Water and Food

Dietary risks from food and water are not of concern.

As part of the assessment process prior to the registration of a pesticide, Health Canada must determine whether the consumption of the maximum amount of residues that are expected to remain on food products when a pesticide is used according to label directions, will not be a concern to human health. This expected maximum amount of residues is then legally established as a maximum residue limit (MRL) under the *Pest Control Products Act* for the purposes of the adulteration provision of the *Food and Drugs Act*. Health Canada sets science-based MRLs to ensure the food Canadians eat is safe.

Reynoutria sachalinensis has long been used as a food item and also consumed for its medicinal values in some parts of the world with no reported adverse effects. There is reasonable certainty that no harmful effects will occur from dietary and drinking water residue exposure to extract of *Reynoutria sachalinensis* from the use of Regalia Maxx Biofungicide Liquid Concentrate. At the time of harvest, the residue level of crops treated with *Reynoutria sachalinensis* is not expected to exceed the natural levels in consumed food or medicinal products. Therefore, no crop residue data are needed and the establishment of an MRL will not be required by PMRA.

While good hygiene practices, such as washing food produce prior to consumption, are not considered in the assessment for the registration of a food-use pesticide, they are recommended as any remaining residues are likely to be reduced by washing and possible cooking of the treated crop before eating.

Occupational Risks From Handling Extract of *Reynoutria sachalinensis*

Occupational risks are not of concern when extract of *Reynoutria sachalinensis* is used according to label directions, which include protective measures.

Occupational exposure to individuals mixing, loading, or applying Regalia Maxx Bioprotectant Liquid Concentrate is not expected to result in unacceptable risk when the product is used according to label directions.

Precautionary (for example, wearing of personal protective equipment) and hygiene statements on the end-use product label aimed at mitigating exposure are considered adequate to protect individuals from any unnecessary risk due to occupational exposure.

Environmental Considerations

What Happens When Extract of *Reynoutria Sachalinensis* is Introduced into the Environment?

The active ingredient, extract of *Reynoutria sachalinensis*, is a naturally occurring constituant of the plant, *Reynoutria sachalinensis* (a.k.a. giant knotweed). As such, it is expected to break down completely within a relatively short period of time and, therefore, will not be persistent in the environment. Extract of *R. sachalinensis* is not expected to cause adverse effects to non-target terrestrial and aquatic organisms.

Value Considerations

What Is the Value of Regalia Maxx Biofungicide Liquid Concentrate?

Regalia Maxx Biofungicide Liquid Concentrate is a biological fungicide that suppresses diseases on a wide variety of plants.

By activating plant defences, Regalia Maxx Biofungicide Liquid Concentrate elicits the plant to defend itself against multiple fungal and bacterial pests through the accumulation of phenolic compounds. Preventative application of this product will suppress plant diseases and is most appropriate for use under low disease pressure. Resistance to the active ingredient is unlikely to develop. This product has the potential to become an integral part of an Integrated Pest Management (IPM) program, especially for organic growers.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental healthh. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of Regalia Maxx Biofungicide Liquid Concentrate to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

The statements, "WARNING: EYE IRRITANT" and "CAUTION: SKIN IRRITANT" are required on the principal display panel.

The existing or additional precautionary statements on the secondary display panel of the label include, "Causes moderate eye irritation, May irritate skin, may cause irritation of the respiratory tract, DO NOT get in eyes, avoid contact with skin or clothing, and avoid inhaling/breathing spray mist."

Mixer/Loader/Applicator and related workers are required to wear a long-sleeved shirt, long pants, shoes plus socks, waterproof gloves, and goggles or face shield when handling, mixing/loading or applying the product, and during all clean-up/repair activities.

The label is required to include the restricted-entry statement, "Do not re-enter or allow entry into treated areas until the spray is dried."

Applicators/workers in greenhouses must wear a NIOSH approved respirator, proper protective clothing, shoes plus socks, water-proof gloves, and protective eye-wear when using high pressure sprayers or when entering a treated area before thorough ventilation and clearing of spray mist.

Keep unprotected persons out of the treated areas in a greenhouse for the duration of the treatment period

Allow entry or re-entry to greenhouse only after thorough ventilation and spray mist or fog has cleared and the treated surface has dried.

Environment

No mitigative measures are required for the proposed use of Regalia Maxx Biofungicide Liquid Concentrate.

Other Information

The relevant test data on which the decision is based (as referenced in PRD2011-14 — *Extract of Reynoutria sachalinensis)* are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection[5] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of the Health Canada's website (Request a Reconsideration of Decision, www.hc-sc.go.ca/cps-spc/pest/part/protect-proteger/public-regist/index-eng.php#rrd) or contact the PMRA's Pest Management Information Service).

5 As per subsection 35(1) of the *Pest Control Products Act.*